K110565

SEP - 1 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:	BIOMET *3i* 4555 Riverside Drive Palm Beach Gardens, FL 33410
Establishment Registration Number:	1038806
Contact:	Jose E. Cabrera Sr. Manager, Regulatory Affairs BIOMET 3i 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel. 561-776-6840 Fax. 561-514 6316 Email jose.cabrera@biomet.com
Date Prepared:	08/27/2011
Trade/Proprietary Name:	Encode Patient Specific Abutment with Nobel Replace Connection
Common/Usual Name:	Dental Implant Abutment
Classification Name:	Abutment, implant, dental, endosseous
Device Classification/ Code:	Class II 21 CFR §872.3630 / NHA
Predicate Device:	K020646, Nobel Replace HA Coated Implant K053654, Atlantis Abutment for Nobel Replace Interface K023113, Replace TiUnite Endosseous Implant
Performance Testing:	Performance testing was conducted as per Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental

	Abutments. Performance testing was based on a comparison between proposed and predicate implant/abutment systems. The results were equal or better than established acceptance criteria, when predicate testing was used as a baseline. Compatibility testing for the abutment will be performed every 6 months.
Device Description:	BIOMET 3i Encode Patient Specific Abutment for Nobel Replace Connection can be compared to current Encode Patient Specific abutments. The change to this device is only to the connection that is intended to interface which is identical to the interface found on the Nobel Replace HA Coated Implant. This feature does not modify the intended functionality of the implant/abutment system. This device is also intended for dental laboratories to provide limited design input to match the anatomical requirements of the patient. Maximum angulation for the abutment is limited to 15^{o}.
Indications for Use:	BIOMET 3i Dental Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained to the abutment.
Technological Characteristics	BIOMET 3i Encode Patient Specific Abutment for Nobel Replace Connection is milled from titanium alloy, is attached to a dental implant and is indicated for the same intended use as the predicated devices reference within this pre-market notification.
Conclusion:	BIOMET 3i Encode Patient Specific Abutment for Nobel Replace Connection is substantially equivalent to the legally marketed predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jose E. Cabrera
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BIOMET 3i, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

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Re: K110565
Trade/Device Name: BIOMET 3i Encode Patient Specific Abutment for Nobel Replace Connection
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 29, 2011
Received: August 31, 2011

Dear Mr. Cabrera:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110565

Device Name: **BIOMET 3i Encode Patient Specific Abutment for Nobel Replace Connection**

Indications for Use: BIOMET *3i* Dental Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained to the abutment.

Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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